

REMARKS

In view of the following remarks, the Examiner is requested to allow Claims 21-34 and 42-43, the only claims pending and under instant examination.

In the Advisory Action, the Examiner asserts that the previous amendment to Claim 43 introduce new matter to the application.

Claim 43 was amended to recite that the cleaved tag is detected "away from said extension product, wherein said extension product is not separated from said single stranded template nucleic acid."

It is again submitted that support for this amendment may be found at least, for example, in part (a) and (b) of claim 43 as present prior to the amendment of the Claim 43. These parts read:

- (a) hybridizing a primer nucleic acid to a single stranded template nucleic acid in a sample;
- (b) extending said primer nucleic acid by at least one complementary nucleotide to produce a extension product that includes a 3' cleavable tag, wherein said at least one complementary nucleotide includes a 3' cleavable tag;

In addition, page 6, lines 1 to 15, provide additional support for the language questioned by the Examiner.

As such, it is submitted that the amendment to Claim 43 previously submitted does not introduce new matter to the application and its entry by the Examiner is requested.

Claim Rejections – 35 U.S.C. § 102

Claims 21-31, 33-34 and 42-43 remain rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Schmidt et al. (WO 99/02728). This rejection is traversed for at least the reasons set forth below.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

In the Final Office Action, the Examiner asserts that "based on the disclosure [in Applicants'] specification, prior to cleavage of the tag from the extended base on the DNA template, the excess, unincorporated cdNTPs are preferably removed from the extension reaction..." The Examiner concludes that "there is some type of separation of the extension products from the extension reaction before cleavage of the tag."

Applicants must respectfully point out that this argument contains an incorrect interpretation of the term "extension product."

An extension product is defined in the claims as the complementary sequence that results from hybridizing a primer nucleic acid to a single stranded nucleic acid template and extending this primer by at least one nucleotide base (complexed with 3' cleavable tag), the base being complementary to the single stranded template. This double stranded hybridization pair is iteratively washed to remove excess bases after each complementary nucleic acid is added to the template. These washes do not involve separating the extension product from the template strand. After each wash, the tag is cleaved for analysis from the extension product while the extension product remains hybridized to the template strand.

Schmidt teaches dissociating the extension product from the template nucleic acid to produce a population of single stranded extension products (oligonucleotides), which are washed in a single step.

In contrast, the extension product of the claimed method is not dissociated from the template nucleic acid prior to analysis.

Accordingly, Schmidt does not teach the element of cleaving the tag from "an extension product that includes said at least one complementary nucleotide hybridized to said template nucleic acid sequence."

Schmidt cannot anticipate the claimed subject matter because it fails to teach every element of the rejected claims. Hence, the Applicants respectfully request that the rejection of claims 21-31, 33-34 and 42-43 under 35 U.S.C. § 102(b) be withdrawn.

Claim Rejections – 35 U.S.C. § 103

Claim 32 remains rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Schmidt (WO 99/02728) in view of Cheeseman (U.S.P.N. 5,302,509).

The Office acknowledges that Schmidt is deficient in that it fails to teach a fluorescent cleavable tag. The Office relies upon Cheeseman to supply this missing teaching in Schmidt. However, as set forth above, Schmidt is further deficient in that it fails to teach or suggest the fundamental element claim 21, which specifies cleaving a tag from "an extension product that includes said at least one complementary nucleotide hybridized to said template nucleic acid sequence."

As Cheeseman was cited solely for its disclosure of a fluorescent cleavable tag, it fails to compensate for the major deficiencies of Schmidt. *A prima facie* case of obviousness has not been established because the recited combination fails to teach every element of claim 32. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 103(a) be withdrawn.

Claim Rejections – 35 U.S.C § 112, first paragraph

Claim 43 has been rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing new matter. This rejection is addressed by amendment and may be withdrawn.

CONCLUSION

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone Bret Field at 650-327-3400.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-1078, order number 10010632-3.

Respectfully submitted,

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By: 

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